REMARKS

Applicants respectfully request reconsideration and allowance of this application in view of the amendments above and the following comments.

Claims 8-10, 12 and 18 were rejected under 35 USC § 112, second paragraph, as being indefinite. In response to the rejection of claims 8-10 and 18, Applicants respectfully point out that it is well known in the art that implants can take on any desired shape or form. See, merely, for example, paragraph [0047] of US 20010018614. While the Examiner is correct that tablets are often administered to patients orally, persons skilled in the art of implants are well aware that tablets are often implanted as well. Below is the abstract from the *Journal of Biomedical Materials Research, 9:* 355-366 (1975), copied from the Wiley InterScience® website:

Article

Biocompatible implants for the sustained zero-order release of narcotic antagonists

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ABSTRACT

Implantable, sustained release drug delivery devices offer benefits not obtained through oral ingestion or injection. These include delivery at a constant therapeutic rate, thus avoiding adverse intermittent and massive dose effects, as well as reliance upon patients taking their prescribed dosages. The drawbacks to their widespread acceptance have been their inability to maintain a zero-order release rate over an extended period of time and poor biocompatibility. Devices capable of satisfying these requirements have been developed and tested extensively for *in vitro* release of the narcotic antagonist cyclazocine. By using implant models prepared from Hydron, a hydrophilic polymer known to exhibit excellent tissue compatibility, we have found that the release rate could be precisely regulated by proper geometry, copolymer composition, concentration of ionogenic groups and cross-link density. Devices in such varied forms as capusles, barrier-film coated tablets and bulk polymerized rods have been tested *in vitro* for periods approaching 1 year.

This abstract explains that devices such as capsules, barrier-film coated tablets and bulk polymerized rods offer advantages when implanted over the same devices administered through oral ingestion or injection. These advantages include delivery at a constant therapeutic rate and guaranteeing that the patient will receive the prescribed dosage.

The pharmaceutical preparation of claim 3 can be formulated as a controlled-release antibiotics drug. That same pharmaceutical preparation can be formed into or coated onto molded bodies, fibers, knitted fabrics, fleece, tablets, powders, etc. When these materials are then implanted into a patient, they will release the antibiotics in a controlled-release manner in accordance with the teachings in the instant specification.

Respectfully, there is nothing unusual about the particular forms that Applicants have claimed from the standpoint of what is customary in the implant art. Therefore, Applicants respectfully submit that the Examiner should reconsider and withdraw this particular aspect of this rejection.

With respect to claim 12, the Examiner's point is well-taken. Accordingly, Applicants have limited claim 12 to molded bodies, thereby providing a further limitation of the subject matter of claim 7.

In view of the foregoing, Applicants submit that the Examiner would be fully justified to reconsider and to withdraw this rejection altogether. An early notice that this rejection has been reconsidered and withdrawn is, therefore, earnestly solicited.

Applicants believe that the foregoing constitutes a bona fide response to all outstanding objections and rejections.

Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Early and favorable action is earnestly solicited.

Respectfully submitted,
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By _____

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